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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/073,881	05/06/1998	MAHENDRA S. RAO	T4903.CIP	1335

7590

11/23/2001

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EXAMINER
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HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/23/2001

19

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/073,881

Applicant(s)

Rao et al

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Aug 24, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-6, 8-13, and 15 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-6, 8-13, and 15 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

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## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on 8/24/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/073881 is acceptable and a CPA has been established. An action on the CPA follows.
2. The rejection of claims 6-7 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the amendment of the claims.
3. Applicant's arguments filed 8/24/01 have been fully considered but they are not deemed to be persuasive.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 2-5 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Note that base claim 1 already requires a "laminin-coated substrate".

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6. Claims 1-6, 8-13 & 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of plating dissociated cells on a fibronectin substrate and a purification step on obtaining “pure, homogeneous populations of neuroepithelial cells”, etc., does not reasonably provide enablement for a method requiring “isolating a pure, homogeneous population of mammalian neural stem crest cells” by replating neuroepithelial cells onto laminin-coated or undefined substrates while removing FGF and/or chick embryo extract; especially when such methods alternatively result in a mixed population of more differentiated cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims, for the reasons made of record in Paper No. 13, and as follows.

Applicants’ arguments on pages 6-7 of the response, as it relates to the developmental stages for mammalian neural tube closure being known in the art, are persuasive.

Applicants then argue on pages 7-8 that the method described in Examples 5-7 of the specification, in which differentiation occurred beyond the neural crest stem cell, uses steps different from the claimed method, and therefore, “these Examples are not relevant to the instant claimed invention and provide no reason to doubt the objective truth of statements in the specification that the method as claimed will generate neural crest stem cells”. However, the previous rejection also cited the teachings from Kalyani et al (1997), which indicated that replating neuroepithelial cells onto laminin substrates, and/or removing FGF and/or chick embryo extract does not result in a population of neural crest stem cells (i.e., especially as it

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relates to pages 219-220; as it relates to claim 1). It is noted that Applicants do not address this aspect of the rejection. Moreover, as previously made of record, Examples 5-7, Figure 1 and page 10 describe how withdrawal of CEE (i.e., as it relates to claim 1) or use of a “laminin-coated substrate” both lead to differentiation to motoneurons or glial (i.e., as it relates to claims 1 & 15); thereby, contradicting the recited method steps for “generating said neural crest stem cells”. Note page 24, lines 7-8 further state that “[l]aminin was used as a substrate instead of fibronectin because laminin has been shown to promote proliferation *and neuronal differentiation*” [emphasis added] (i.e., differentiation beyond neural crest stem cells). Additionally, page 22, lines 14-16, describes how use of a “fibronectin-substrate... in addition [gave rise to] a small percentage of GFAP-immunoreactive cells (1-5%)”, which are not neural crest cells, by definition (i.e., as it relates to claim 15). Therefore, Applicants’ remaining arguments are not persuasive.

Lastly, because the metes and bounds of the recitation, “dorsalizing agent” is unknown, in that the specification lists only three examples (i.e., as it relates to claims 1 & 9), it would require undue experimentation for the skilled artisan to know how to make the invention as currently claimed; thereby, not meeting the enablement requirements under 35 U.S.C. 112, first paragraph.

7. Claims 1-6, 8-13 & 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In particular, it appears a “pure homogeneous of mammalian/rat neuroepithelial stem cells” will not be obtained from that recited in steps (a) (i)-(iii), because no purification step is recited to obtain such. In other words, it appears the recited method steps alternatively would result in a mixed population of cells (e.g., see page 22, lines 14-16; Figure 1; Examples 5-7; page 10) . For example, a step requiring “antibody capture” may be required. Therefore, the method as currently recited is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Note further that claim 1 (a)(iii) and claim 15 (a)(iii) should read “feeder-cell-independent culture for proper antecedent basis with page 9 of the specification.

8. Claims 1-6 & 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the metes and bounds of the recitation, “dorsalizing agent” is ambiguous, in that the specification lists only three examples (i.e., as it relates to claims 1 & 9).

9. Claims 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

No antecedent basis for the recitation of “mitogen” exists in base claim 1.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.  
November 14, 2001

  
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SUPERVISORY PATENT EXAMINER  
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